IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., et al.,	:	
	:	
Plaintiffs,	:	
	:	**Civ. No. 12-3824**
v.	:	**CONSOLIDATED**
	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
	:	
	:	
Defendants.	:	
	:	

PLAINTIFF MYLAN PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT AS TO DEFENDANTS' ANTITRUST LIABILITY

Pursuant to Federal Rule of Civil Procedure 56, and for the reasons set forth in the attached Memorandum of Law, Plaintiff Mylan Pharmaceuticals, Inc. respectfully requests that the Court grant this Motion for Summary Judgment finding Defendants Warner Chilcott PLC and Mayne Pharma Ltd. in violation of the Sherman Act.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel for Plaintiff Mylan Pharmaceuticals, Inc. hereby certifies that a true and correct copy of PLAINTIFF MYLAN PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT AS TO DEFENDANTS' ANTITRUST LIABILITY (with supporting Memorandum and exhibits) was served this day via email, and a copy with exhibits was hand delivered to the Court.

Dated: March 10, 2014

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., **Plaintiff,**	:	
v.	:	**Civ. No. 12-3824** **CONSOLIDATED**
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	
ROCHESTER DRUG CO-OPERATIVE, INC., **Plaintiff,**	:	
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	
MEIJER, INC., et al., **Plaintiffs,**	:	
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	
AMERICAN SALES COMPANY, LLC, **Plaintiff,**	:	
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	

MEMORANDUM IN SUPPORT OF PLAINTIFF MYLAN PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT AS TO DEFENDANTS' ANTITRUST LIABILITY

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I. INTRODUCTION

The Sherman Act stands as a "consumer welfare prescription," condemning conduct that obstructs "competitors['] . . . freedom to compete" and causes "[p]rice [to be] higher and output lower than they would otherwise be[.]" *See Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (quoting ROBERT H. BORK, THE ANTITRUST PARADOX 66 (1978)); *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 106-07 (1984). This case concerns just such conduct. From the beginning of their relationship in 1997, Warner Chilcott and Mayne agreed to an "anti-generic strategy" of making tactical modifications to their delayed-release doxycycline hyclate acne medication, Doryx. They successfully executed the strategy by switching the product from a capsule to a tablet form in 2005 (just as generic entry was about to occur) and then performing multiple additional product switches to continue delaying generic entry.

Because of their strategy, generic competition for Doryx did not enter the marketplace in any meaningful way until 2011, and Defendants improperly reaped years of additional supracompetitive profits at the expense of rivals and consumers. Their conduct presents a "paradigmatic" example of branded pharmaceutical companies gaming the pharmaceutical regulatory system to achieve the "patently anticompetitive" aim of preventing entry of AB-rated generic competition. *See* Ex. 1, Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 714-16 (2009).[1] Analyst reports have described Defendants' conduct as a "ploy and [a] gimmick" that successfully excluded competitors from the market. Ex. 2, Rubinfeld Rpt. ¶¶ 93-95; Ex. 3, MYLAN-00602988, at 988. Their "anti-generic strategy" should, accordingly, be condemned as a matter of law.

Market Power. Both direct evidence and indirect evidence establish as a matter of law that Defendants had sufficient market power to violate Sherman Act Sections 1 and 2, 15 U.S.C. §§ 1 & 2. Dr. Daniel L. Rubinfeld, a distinguished economist with deep expertise in market power issues, offers a comprehensive analysis showing that Defendants maintained prices

[1] All exhibits are attached to Declaration of Jeffrey Bank ISO of Mylan's Motion to Dismiss.

substantially above the competitive level throughout the period of their strategic product switching. This proves Defendants' market power through direct evidence. Dr. Philip B. Nelson, also a widely-published economics expert, provides a further economic analysis showing that delayed-release doxycycline hyclate, at a minimum, comprises a well-defined antitrust sub-market under *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962), protected by high barriers to entry in which Defendants held a 100% share prior to generic entry and still hold a [redacted] share.

Defendants' responsive analysis from Dr. Sumanth Addanki simply fails to rebut this compelling evidence. Applying an idiosyncratic definition of market power for this case, Dr. Addanki rejects standard economic analysis of direct and indirect evidence, instead offering analyses that run entirely contrary to settled law and good economic practice. His opinions are inadmissible for the reasons noted in Mylan's *Daubert* motion, and at a minimum they do not create a triable issue as to Defendants' market power.

Anticompetitive Conduct. Under the rule of reason, Mylan bears the initial burden of showing harm to competition from Defendants' conduct. *United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001) (en banc). It can discharge this burden with ease because "the anticompetitive effects of [generic pharmaceutical] exclusion cannot be seriously debated." *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003). The evidentiary record is conclusive that Defendants' strategic product changes delayed generic entry, and that earlier generic entry would have resulted in major price reductions to consumers. Indeed, the evidence is so overwhelming that Defendants' economic expert on competitive effects, Dr. Dennis Carlton, has simply advocated for a *per se* rule that product changes cannot be anticompetitive. This is contrary to law, *Microsoft*, 253 F.3d at 64, and therefore cannot suffice to create a triable issue as to whether Defendants' conduct harmed competition.

Invalid Defenses. Because of the clear anti-competitive effects of Defendants' strategic product changes, they bear the burden of establishing legitimate business justifications for their conduct. *Microsoft*, 253 F.3d at 59, 67. They cannot do so. Each of their claimed benefits from their product hopping strategy collapses under close scrutiny. For example:

- The uncontroverted evidence is that the capsule to tablet switch did not materially improve the safety or stability of the Doryx product. Notably, Defendants only pursued this strategy in the U.S. (where they faced imminent generic competition); they continue to market capsules elsewhere. Further, the shelf life labeling for the tablets was the same as for the capsules, meaning there was no improvement for end-users.
- The various dosing changes provided little or no benefit to consumers as multiple doses created by the changes had no labeled use and several of the switches eliminated what were previously standard doses for Doryx. Indeed, the repeated shifting of dosages created confusion in the market. Moreover, any problems that the post-tablet switches did solve were simply the by-product of Defendants' initial anticompetitive switch to tablets, meaning they cannot support a business justification defense.
- Any claims of "free-riding" are also insufficient. The Hatch-Waxman Act and state substitution laws establish and endorse the abbreviated development pathways and automatic generic substitution Defendants deride as "free-riding," and they cannot claim as a pro-competitive justification their desire to block the most efficient pathway for generic entry and distribution.

Moreover, as a matter of law, Defendants are separate economic actors capable of conspiring under *American Needle, Inc. v. National Football League*, 560 U.S. 183 (2010).

Antitrust Injury. In sum, Defendants' conduct was intended to, and successfully did, obstruct competition and maintain high prices for Doryx, without providing meaningful consumer benefits. Mylan plainly suffered antitrust impact because Defendants cannot contest that Mylan brought its generic to market later (and at greater expense) than it would have had Defendants not engaged in their "anti-generic strategy." All of Defendants' injury arguments go to the amount of damages, not the fact that their conduct caused injury to Mylan's "business or

property[.]" *See* Clayton Act § 4, 15 U.S.C. § 15(a). Mylan is thus entitled to judgment as a matter of law that Defendants are liable for their antitrust violations.

II. STATEMENT OF UNDISPUTED FACTS

A. The Hatch-Waxman Act and State Substitution Laws Have Substantially Increased Access to Lower Cost Generics

In order to obtain FDA approval to market a new drug, a company is required to file a New Drug Application ("NDA") showing the drug's safety and efficacy.[2] Prior to the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), generic companies had to use the same NDA process without any of the market exclusivity incentives enjoyed by the typical brand drug, so there was no effective FDA approval process for generic drugs and virtually no generic market.[3] Thus, before 1984, generics accounted for only 19% of prescriptions.[4] Representative Waxman explained that "[t]he lack of [abbreviated] procedures [was] an effective bar to generic competition because the generic companies cannot afford the millions of dollars to duplicate the test results already in the FDA's files."[5]

The Hatch-Waxman Act provided greater access to low cost generic drugs, while also incentivizing investment in pharmaceutical innovation.[6] The purpose of Title I of the Act was "to make available more low cost generic drugs," and the purpose of Title II was "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."[7] Senator Hatch noted that the law "combines a

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[2] *See* 21 U.S.C.§ 355(b)(1)(A).
[3] *See* Ex. 4, Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 Antitrust L.J. 585, 586-90 (2003); Ex. 5, Johnston Rpt. ¶¶ 24-27. *See also* Ex. 6, Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at ix (1998) (hereinafter, "CBO Report").
[4] Ex. 6, CBO Report, at ix and xii.
[5] *See* Ex. 7, 130 Cong. Rec. H8701-13, at H8706 (daily ed. August 8, 1984) (remarks of Rep. Henry A. Waxman).
[6] *See id.*
[7] *See* Ex. 8, Schilling Dep. Ex. 2, at 1-2, H.R. Rep. 98-857(I) (June 21, 1984).

relaxation of federally imposed barriers to competition by generic drug manufacturers with added stimulus for research on new drugs and medical devices[.]"[8]

In order to increase access to lower cost generic drugs, the Hatch-Waxman Act created an abbreviated, less costly FDA review process for generic drug applications (Abbreviated New Drug Application, or "ANDA"), allowing generic drugs to gain approval by establishing bioequivalence and pharmaceutical equivalence to a reference listed brand drug ("RLD").[9] If a generic drug meets these standards, it is given an AB-rating to the RLD.[10]

State generic substitution laws work in tandem with the FDA therapeutic rating system to "create a regulatory framework designed to reduce costs for consumers by lowering generic costs and increasing the role of price at the retail pharmacy counter."[11] Most states rely on the FDA's rating in determining whether a lower cost generic may be substituted by a pharmacist when presented with a prescription for a branded drug, and in many of those states substitution is mandatory when an AB-rated generic drug is available.[12]

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[8] Ex. 9, 130 Cong. Rec. S6978-85 (daily ed. June 12, 1984) (statement of Sen. Orrin Hatch).

[9] *See* 21 U.S.C. §§ 355(j)(2)(A)(vii), (5)(B)(iii-iv). A pharmaceutically equivalent product must "contain the same active ingredient(s), [be of the] same dosage form, [have the same] route of administration and [be] identical in strength or concentration." Ex. 10, U.S. Dep't of Health and Human Servs. & FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, at vi-vii (34th ed. 2013) (hereinafter "Orange Book"), *available at* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf. A drug is bioequivalent when "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions[.]" 21 U.S.C. § 355(j)(8)(B)(i).

[10] Ex. 10, Orange Book, at vii. The FDA uses a rating system to denote the relationship between pharmaceutical products. As described above, an AB rating means that a generic drug has been shown to be therapeutically equivalent to the brand drug it references in its ANDA. *Id.*

[11] FTC Br. as *Amicus Curiae*, Dkt. No. 116-2, at 7 (hereinafter "FTC Amicus"). *See also* Ex. 11, *Drug Legislation Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, on drug labeling and advertising, H.R. 1554 and new drug application, H.R. 3605*, 98th Cong., 1st Sess. 1 (July 25, 1983); Ex. 10, Orange Book, at iv. *See also* Ex. 12, Reisetter Dep. at 74:5-75:15.

[12] *See* Ex. 13, Jesse C. Vivian, *Generic-Substitution Laws*, U.S. Pharmacist (Jun. 19, 2008), *available at* http://www.uspharmacist.com/content/s/44/c/9787/; Ex. 14, *State Regulations on Generic Substitution*, Pharmacist's Letter 2006, 22(9):220901 (updated April 2009); s*ee also* Ex.

(continued...)

"The Hatch-Waxman Act and state substitution law reforms have been remarkably successful in facilitating generic competition and generating large savings for patients, health care plans, and federal and state governments."[13] The fact that generic products have an abbreviated FDA approval process and can be distributed through automatic substitution at the pharmacy level has allowed generic manufacturers to offer therapeutically equivalent drugs at a significantly lower cost.[14] The FDA Director of the Office of Generic Drugs has testified that "[t]he Hatch-Waxman Amendments have been very successful and have provided for the approval of over 8,000 generic drug products. These products are lower cost, high quality products that have saved the American public and the government billions of dollars."[15] By 2011, nearly 80% of prescriptions were filled with generic drugs, with an estimated annual savings of $192.8 billion in 2011 and $1 trillion over the prior ten years.[16]

(...continued from previous page)
10, Orange Book, at iv. All fifty states and the District of Columbia have enacted laws or regulations that permit, encourage, and in some circumstances require pharmacists to substitute AB-rated generics. Ex. 15, Schondelmeyer Rebuttal Rpt. ¶ 23. Most states only allow pharmacists to substitute AB-rated drugs. *Id*. at ¶¶ 23-30.

[13] FTC Amicus, at 7.

[14] *See, e.g.*, FTC Amicus, at 4-7; Ex. 6, CBO Report, at ix. *See also* Ex. 12, [redacted] Ex. 5, Johnston Rpt. ¶¶ 24-27; Ex. 15, Schondelmeyer Rebuttal Rpt. ¶ 22.

[15] Ex. 16, *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs: Hearing Before the Special Special Comm. On Aging, United States Senate*, 109th Cong., 2d Sess. (July 20, 2006) (Statement of Gary Buehler, R.Ph., Director of FDA Office of Generic Drugs), *available at* http://www.hhs.gov/asl/testify/t060720.html; *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998) ("Congress's central goal, in enacting the Hatch-Waxman Amendments, [was] to bring generic drugs onto the market as rapidly as possible.").

[16] Ex. 17, Generic Pharmaceutical Ass'n, *Savings, $1 Trillion Over 10 Years: Generic Drug Savings in the U.S.*, at 2-3 (4th ed. 2012) *available at* http://www.gphaonline.org/media/cms/IMSStudyAug2012WEB.pdf.

B. Doryx Was Marketed As a Unique Product and Was Not Price Sensitive to Non-AB Rated Products

Defendants have marketed Doryx as unique and superior to other medications indicated for treating acne.[17] [redacted][18] Entry of AB-rated generics, when it finally occurred, had a significant impact on Defendants' market share and the overall price of delayed-release doxycycline hyclate.[19]

1. Doryx is a Unique Product

Doryx uses enteric coated pellets that bypass the stomach and are released and absorbed in the small intestine.[20] The coating ensures that the pellets do not release doxycycline into the stomach, which can cause gastrointestinal irritation.[21] While there are other oral antibiotics for treating acne,[22] Doryx is differentiated in many respects.[23]

Doryx is Differentiated From Other Tetracyclines. Doxycyclines, including Doryx, have a favorable side effect profile relative to other tetracycline class antibiotics.[24] [redacted]

[17] *See, e.g.*, Ex. 18, WC1096349 (Marketing Overview, Doryx, July 2005).
[18] *See* Ex. 19, Nelson Rpt. ¶¶ 88-92.
[19] *See, e.g., id.* at ¶ 128 (explaining the effect on pricing and market share from Mylan's entry with the generic 150 mg tablet); *see also* Ex. 20, Rubinfeld Rebuttal Rpt. ¶ 20 (describing the further reductions in price after Heritage also entered the market with AB rated generic Doryx tablets).
[20] Ex. 18, WC1096349, Slide 14.
[21] *Id.*; Ex. 21, MAYNE-00072790, at 790.
[22] Defendants have identified a variety of prescription and non-prescription products used to treat acne, including (1) minocyclines such as Dynacin and Solodyn, (2) doxycycline monohydrates such as Adoxa and Monodox, and (3) generic forms of these products. *See* Ex. 22, Declaration of William Poll (former Warner Chilcott employee), May 15, 2013, ¶¶ 8-9.
[23] *See, e.g.*, Ex. 18, WC1096349, Slides 2, 13-14.
[24] Ex. 23, WC0745507, Slides 15-42; Ex. 18, WC1096349, Slides 13-14.
[25] Ex. 23, WC0745507, Slides 22, 27; Ex. 18, WC1096349, Slide 13.

[redacted][26] Independent clinical research confirms that Doryx is differentiated from other tetracyclines.[27]

Doryx is Differentiated From Other Doxycyclines. All doxycyclines have the potential to cause nausea or gastrointestinal irritation; Doryx is the only one that has a delayed-release coating that prevents the active ingredient from releasing until it reaches the small intestine thereby reducing the side effects.[28] This delayed release property works to avoid the gastric discomfort that is common with all other doxycycline products (all of which are immediate release).[29] Warner Chilcott marketing materials highlight the distinctions between other doxycycline products and Doryx, [redacted][30]

Doryx was not price sensitive to non-AB-rated products. [redacted]

[26] Ex. 23, WC0745507, Slide 36.
[27] Ex. 24, Meghan Gannon, et al., *Which Oral Antibiotics are Best for Acne?*, The Journal of Family Practice, Vol. 60, No. 5 (May 2011), at 290.
[28] Ex. 18, WC1096349, Slide 14.
[29] *Id.*
[30] Ex. 23, WC0745507, Slide 19.
[31] *See* Ex. 19, Nelson Rpt. ¶¶ 93-107.
[32] Ex. 25, WC3156182, at 185.

[redacted][33]

An analysis of Doryx's pricing and sales demonstrates that Doryx was not price sensitive to other products. For example, Solodyn (branded minocycline) was introduced in 2006 and was priced much higher than Doryx.[34] [redacted][35] [redacted][37]

2. Lacking Competition from AB-Rated Equivalents, Consumers Paid Higher Prices for Doryx

It is widely accepted that competition from AB-rated generic manufacturers results in market share moving to lower priced generics, with generic market share growing and generic prices dropping as more generics enter the market and compete on price.[38] As described below, the parties' contemporaneous documents and deposition testimony reflect this market reality.

Market-wide prices are impacted to a greater extent by AB-rated products than other non-AB-rated products. Generally, AB-rated generic versions of a brand drug quickly gain a

[33] *Id.*
[34] Ex. 26, WC0745518, at Slide 69; Ex. 27, WC0029578.
[35] [redacted]
[36] Ex. 29, Webster Dep. 31:3-33:21.
[37] *Id.* at 54:4-56:3.
[38] *See* Ex. 2, Rubinfeld Rpt. ¶ 16 (summarizing the findings of "extensive and widely-cited economics literature that examines the effects of competition between brand-name and generic drugs made possible by the Hatch-Waxman regulatory framework."); Ex. 15, Schondelmeyer Rebuttal Rpt. ¶ 58 (noting that this "predictable pattern . . . . has been extensively studied and is generally accepted as an inherent feature of the pharmaceutical industry."); Ex. 6, CBO Report, at xiii.

large share of the market upon entry, and the generic drugs are priced at a substantial discount to the brand.[39] The first AB-rated generic competitor will be priced at a modest discount, but as additional AB-rated generics enter the market, the prices reach 20% or less of the brand price.[40] AB-rated generics impact market-wide pricing to a greater extent than both other brand drugs and non-AB-rated generics due to the framework created by the Hatch-Waxman Act and state substitution laws.[41]

[redacted]

[39] Ex. 6, CBO Report, at 28. The more generics that enter the market, the more pressure to lower prices in order to maintain market share. *Id*. at 32. [redacted]

[40] Ex. 15, Schondelmeyer Rebuttal Rpt. ¶ 59. *See also* FTC Amicus, at 7 (discussing that the first generic price is typically 20 to 30 percent off of the brand, and subsequent generic entry creates greater price competition with discounts of 85 percent or more).

[41] *See* Ex. 2, Rubinfeld Rpt. ¶¶ 27-29. *See also* Ex. 6, CBO Report, at 35; Ex. 15, Schondelmeyer Rebuttal Rpt. ¶¶ 51-53.

[42] Ex. 31, MA-0146072, at 74.

[43] Ex. 32, WC1069390 at 393; *see also*, Ex. 33, WC1486561, at 561, 573.

[redacted][44]

Similarly, Mylan's forecasts projected that it would enter at prices below branded Doryx, with the price disparity growing as more generics enter the market.[45] [redacted][46] When Mylan did enter with an AB-rated generic Doryx, it was [redacted] and took substantial sales from the brand product.[47] And, when another AB-rated generic product entered, prices for generic Doryx dropped even more.[48]

C. Defendants Engaged In An Anti-Generic Strategy That Has Repeatedly Impeded The Entrance Of AB-Rated Generic Competitors, Such As Plaintiff Mylan

It is beyond genuine dispute that, since 1997, Defendants have agreed to and jointly pursued a strategy to block AB-rated generic competition in the U.S. by gaming the U.S. regulatory system.[49] Over the course of just a few years, Defendants changed the product form, discontinued the prior form, added and subtracted instructions on the label, introduced and discontinued multiple dosages, and incrementally added physical scores to the product.[50]

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[44] Ex. 33, WC1486561, at 561; *see also* Ex. 34, MA-0097917, Slide 9.

[45] *See, e.g.*, Ex. 35, MYLAN-02069058; Ex. 36, MYLAN-02068924; Ex. 37, MYLAN-02068590; Ex. 38, MYLAN-02068591.

[46] [redacted]

[47] *See* Ex. 19, Nelson Rpt. ¶ 128.

[48] *See* Ex. 20, Rubinfeld Rebuttal Rpt. ¶ 20.

[49] [redacted]

[50] A timeline summarizing the changes can be found at Ex. 2, Rubinfeld Rpt., Ex. 1.

1. Defendants Spent Millions of Dollars to Swap Capsules for Tablets for the Strategic Purpose of Preventing Generic Competition

In 1985, Mayne (formerly known as Faulding) received U.S. approval for the 100 mg Doryx capsules[51] [redacted][57]

Tablet development, approval, and launch. [redacted][59] Defendants jointly pursued the

[51] Ex. 45, MA-0122172, at 175
[52] Ex. 46, WC3663349, at 350-81.
[53] Ex. 47, WC0027016, at 017.
[54] Ex. 48, WC2043655, at 655-77. In 2001, Defendants were granted approval to sell 75 mg capsules alongside the 100 mg capsules. *See* Ex. 45, MA-0122172, at 175.
[55] Ex. 49, MA-0699848, at 861.
[56] Ex. 50, MA-0266442, at 452.
[57] Ex. 51, Boissonneault Dep. Ex. 9, WC2043678, at 680.
[58] Ex. 52, MA-0261772.
[59] Ex. 53, MAYNE-00179217 (emphasis added); *See also* Ex. 54, WC0021812, at 815.

tablet [redacted] [60] Warner Chilcott filed the NDA for the 75 mg and 100 mg tablets in April 2004; it was approved on May 6, 2005, and Defendants launched the tablets in September 2005.[61]

Market switched from capsules to tablets. [redacted] [62] By August 19, 2005, [redacted] [63] and they began to actively market against additional sales of Doryx capsules. [redacted] [64] [redacted] [65] [redacted] [66] and informing [redacted] that Doryx capsules were no longer available.[67] [redacted] [68]

Tablet switch involved significant investment of time and money. [redacted]

[60] Ex. 54, WC0021812, at 815.
[61] Ex. 55, WC0173378, at 379; Ex. 56, WC3415615, at 615, 637; Ex. 57, WC0393786, at 786-87.
[62] [redacted]
[63] Ex. 59, WC0417223, at 223.
[64] Ex. 60, WC1096172.
[65] *See* Ex. 61, WC1612151, at 151-53.
[66] Ex. 62, WC1643821.
[67] [redacted]
[68] Ex. 65, WC1096194.
[69] Ex. 66, MA-0067074; *see also* Ex. 67, WC3154909, at 909.

[redacted][75]

Tablets were neither improved nor preferred. Despite Defendants' multi-year, multimillion dollar investment and increased production costs, [redacted]

[70] [redacted]

[71] [redacted]

[72] Ex. 73, WC1578349; Ex. 74, WC1634173, at 173-75.

[73] Ex. 75, Lukas Dep. 52:24-56:20; Ex. 76, Lukas Dep. Ex. 8, at 173-74.

[74] [redacted]

[75] [redacted]

[redacted][76] [redacted]

[redacted][79]

After the tablet switch, it was clear that there were also customers who preferred the capsule. For example, [redacted]

[redacted][81]

The tablet form also caused new and unique patient health issues. In one case, [redacted]

[76] Ex. 85, WC1615975, at 975-76. *See also* Ex. 86, deVries Dep. 60:4-6, 63:6-15, 67:3-13; Ex. 87, Kolassa Dep. 238:16-25, 361:20-362:2.
[77] Ex. 88, MAYNE-00309010, at 010-11.
[78] Ex. 89, WC1649709, at Slide 24.
[79] [redacted]
[80] Ex. 92, WC1649176 (emphasis added).
[81] Ex. 93, MA-0063782, at 785-87.

[redacted][82][redacted]

Additionally, the FDA-approved label for Doryx capsules had an instruction for easily sprinkling the contents of the capsule over applesauce by opening the capsule,[83] but consumers lost this dosing option when Defendants switched the market to tablets, which could not be easily dosed over applesauce.[84]

Defendants recognized that the swap-out foreclosed generic competition. Shortly after the switch, Sandoz, a generic manufacturer, was granted approval for a generic delayed-release doxycycline hyclate capsule.[85] By then though, Defendants had successfully switched the market to tablets, [redacted][86]

[redacted][87] Independent financial analysts monitoring Warner

[82] Ex. 94, WC0029977, at 977-78.
[83] *See* Ex. 95, WC0163379.
[84] Ex. 96, Howard Dep. 120:6-121:13; Ex. 97, Kibbe Rpt. ¶¶ 54-56; Ex. 98, Kibbe Rebuttal Rpt. ¶ 22.
[85] Ex. 99, SANDOZ-RDC-00003364, at 364, 366.
[86] Ex. 100, MA-0027383. *See also* Ex. 101, WC0389868.
[87] [redacted]

Chilcott have also acknowledged the success of Defendants' product switches in avoiding substantial competition from AB-rated generics and preserving their high profit margins.[88]

2. Defendants Added Score Marks to Their 75 mg and 100 mg Tablets as an [redacted] Against Generic Competition

A score is a line that runs across the surface of a tablet that facilitates the practice of tablet splitting when "less than a full tablet is desired for a dose."[89] From the beginning, Defendants considered [redacted][90]

[redacted][93]

In the summer of 2008, Warner Chilcott filed applications to add score lines to the 75 mg and 100 mg Doryx tablets,[94] and by the first quarter of 2009 the FDA approved scoring of each.[95]

[redacted]

[88] *See* Ex. 105, WC1810187, at 194, "Warner Chilcott Limited," RBC Capital Markets, January 14, 2008, p. 8 ("Facing potential generic entry for its Doryx extended-release capsules . . . management chose to switch the brand from a capsule to a tablet as a preemptive strike. The switch was almost flawlessly executed[.]").
[89] Ex. 106, WC1309813, at 816-17.
[90] Ex. 49, MA-0699848, at 860-62; Ex. 97, Kibbe Rpt. ¶ 67.
[91] Ex. 107, MAYNE-00146556, at 558.
[92] Ex. 108, MA-0042684, at 684.
[93] Ex. 109, WC0437319, at 320.
[94] Ex. 273, WC0171198, at 202; Ex. 111, WC0171051, at 053.
[95] Ex. 112, WC0170256, at 256-57; Ex. 113, WC0170244, at 244-45.
[96] Ex. 114, MA-0450907, at 908.

[redacted] Scored 75 mg and 100 mg tablets were launched by the first quarter of 2009, resulting in dosing options of 37.5 mg, 50 mg, 75 mg, and 100 mg.[97]

3. Defendants Next Moved the Market to the 150 mg Single Scored and Then the 150 mg Dual Scored to Avoid Generic Competition

150 mg single scored product. On December 19, 2007, Warner Chilcott filed a Prior Approval Supplement ("PAS") to add a 150 mg Doryx dose strength to NDA 50-795,[98] [redacted] [100] On June 20, 2008, the FDA approved the 150 mg Doryx Tablets.[101] And, the following month, Warner Chilcott launched the single-scored 150 mg Doryx tablets[102] and [redacted] [103] [redacted]

[redacted]

[97] Ex. 115, WC3206077, at 077; Ex. 116, WC1822514, at 515; Ex. 117, WC1830258. The 37.5 mg dose had no indicated usage. *See* Ex. 118, WC0169132, at 132, 135.

[98] Ex. 119, WC0171428, at 435.

[99] [redacted]

[100] [redacted]

[101] Ex. 126, WC0171127, at 127, 147.

[102] Ex. 127, WC0455106.

[103] *See* Ex. 128, WC3800932 [redacted] Defendants officially [redacted] *See* Ex. 189, WC1089058; Ex. 129, WC1295637.

[redacted][104]

In May 2010 Warner Chilcott's Executive Vice President and Chief Financial Officer, Paul Herendeen, told investors that the company was "able to transfer on about 90% of that franchise into the 150 [mg] versions . . . So we [were] able to protect ourselves."[105] Likewise, an October 2010 financial analyst report noted that "as [Warner Chilcott] has been able to successfully convert over 92% of prescriptions to the 150 mg formulation in anticipation of generic entry at the lower doses, generic entry at these lower strengths will not be a major threat to the Doryx franchise."[106] After the switch, when only the single-scored 150 mg tablet was available, the dosing options were 75 mg and 150 mg.[107] Notably, the recommended labeled dose for Doryx at all times has been 100 mg, a dose that was no longer available.

150 mg dual scored product. By [redacted], the Defendants had begun to develop a dual scored 150 mg tablet that could be divided into three 50 mg tablets.[108] On September 13, 2011, the FDA approved NDA 50-795/S-014 for the dual scored 150mg Doryx tablets,[109] and Warner Chilcott launched the product within days.[110] Defendants were effectively able to switch the market from single-scored to dual-scored tablets by [redacted][111] After the single-scored 150 mg tablet was discontinued, the available dosing options were 50 mg, 100 mg, and

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[104] [redacted].

[105] Ex. 132, WC0562191, at 193.

[106] Ex. 133, WC0567237, at 286.

[107] *See* Ex. 134, WC1587080, at 091; Ex. 135, WC1587060, at 071; Ex. 136, WC1755968, at 968, 971; Ex. 137, WC1310794, at 794, 797.

[108] Ex. 138, MA-0053586-99, at 88; *See* Ex. 139, MA-0693206.

[109] Ex. 140, WC0166527, at 527, 553.

[110] Ex. 141, WC0317754.

[111] *See* Ex. 142, WC0316169; Ex. 143, WC0600726, at 726-28; Ex. 144, WC0351338 (demonstrating shift in sales).

150 mg. A 75 mg dose was no longer available. There was no indication that demand had changed.[112]

[redacted][113] Warner Chilcott also filed a Citizen Petition requesting that the FDA refrain from approving any ANDAs "unless and until the ANDA applicant adopts a dual-scored 150 mg tablet configuration[.]"[114] Defendants claimed that the introduction of a generic single-scored tablet would cause confusion in the market.[115] In denying Defendants' petition, the FDA noted that Defendants themselves had sold both single and dual-scored 150 mg tablets.[116] A contemporaneous analyst report described Defendants' move to the double scored 150mg as a "ploy and [a] gimmick" to avoid generic competition.[117]

Dual scored 150 mg tablets became the priority after FDA approval for a 200 mg tablet was delayed and generic competition was imminent. [redacted][118] Defendants had already developed and filed an application for a 200 mg Doryx tablet formulation.[119] However, on September 29, 2009, the FDA determined they could not approve the application because "there [was] no approved

[112] [redacted]
[113] [redacted]
[114] Ex. 148, WC1307648, at 648.
[115] *Id.* at 651.
[116] Ex. 149, WC1158119, at 123, 126 (the FDA also noted the suspect timing of Defendants' latest switch, "including the fact that the RLD made scoring changes on the eve of expected generic approval[.]").
[117] Ex. 3, MYLAN-00602988.
[118] Ex. 150, MA-0124912, at 913.
[119] Ex. 151, WC0169962, at 966.

indication and dosage that uses 200mg as a dose." [120] [redacted] [121]

In June 2011, Defendants learned that Mylan had received tentative approval for a 150 mg generic Doryx tablet.[122] On July 5, 2011, Defendants still had not gained approval of the 200 mg tablet [redacted] [124]

4. Defendants' Claimed Justifications for the Product Changes are Belied by Contemporaneous Evidence and Witness Testimony

a. Esophageal Safety Claims Do Not Withstand Scrutiny

Defendants will likely argue that the switch to tablets was motivated by risk of esophageal injury from the capsules. As evidence of this concern, [redacted] [125] However, Warner Chilcott, in notifying the FDA of the [redacted] [126] Further, it noted that [redacted]

[120] Ex. 152, WC0169127, at 127.
[121] Ex. 153, MA-0667875, at 875.
[122] *See* Ex. 154, WC1246772, at 772.
[123] Ex. 42, WC0300035, at 036.
[124] [redacted]
[125] [redacted]
[126] Ex. 157, WC0164487, at 88.

[redacted][127] The FDA agreed and never sought withdrawal of the capsules. As discussed below, Mayne has also continued to sell Doryx capsules in other countries, and [redacted][128] In fact, Defendants [redacted] the tablet as an *uncoated* tablet, [redacted][129]

Risk of esophageal-related incidents did not motivate the switch. [redacted][131] In fact, the Package Insert for both Doryx capsules and tablets contain the same adverse event warning: "Rare instances of esophagitis and esophageal ulcerations have been reported in patients receiving capsule and tablet forms of drugs in the tetracycline class."[132]

Nor is there any evidence that esophageal injury is more prevalent with Doryx capsules as compared with tablets. There has been no study comparing the rates of esophageal injury with Doryx capsules as compared to the tablets, [redacted]

[127] *Id.*
[128] *See* Ex. 158, WC0343420 at 420-21; Ex. 159, MA-0443095, at 96; Ex. 155, WC3122868, at 869-70; Ex. 160, MA-0004941 at 41.
[129] [redacted]
[130] Ex. 96, Howard Dep. at 90:10-20.
[131] *Id.* at 96:5-97:4.
[132] Ex. 164, WC0596455, at 456; Ex. 137, WC1310794, at 801.
[133] Ex. 85, WC1615975, at 975-76.

[redacted][137]

Doryx capsules are still sold in other countries. Mayne currently sells Doryx capsules in Australia and Singapore.[138] [redacted][141]

[134] Ex. 165, Ellman Dep. 149:15-50:24.
[135] [redacted]
[136] Ex. 167, WC0067756, at 759.
[137] Ex. 168, MacFarlane Dep. 204:2-18 (emphasis added).
[138] Ex. 169, MaynePharma.com, Doryx Capsules & Tablets, http://www.maynepharma.com/products/current-proprietary-products/doryx-.
[139] Ex. 170, MA-0003535, at 543.
[140] *Id.* at 47-51.
[141] *Id.* at 37.

Moreover, the year before the launch of the Doryx tablets, Defendants were also developing 150mg and 200mg capsules using the same pellets contained in the 75mg and 100mg capsules.[142] There was no mention of any potential esophageal issues. And, although they dropped the development of these products after submitting the NDA for the 75 mg and 100 mg tablets, Defendants continued to consider the possibility of re-launching a Doryx capsule. In the summer of 2011, Defendants discussed re-launching the Doryx 75mg and 100mg capsules, as well as a 150mg capsule.[143]

b. Claims Regarding Stability Do Not Explain Defendants' Conduct

Defendants may argue that the tablet provided for improved stability over the capsule based on two [redacted][144] [redacted][149]

[142] Ex. 171, MAYNE-00007380, at 381.
[143] [redacted]
[144] *See, e.g.*, Ex. 174, Illum Rpt. ¶¶ 59-64.
[145] Ex. 175, WC3153807; Ex. 176, WC0164115, at 115-16; Ex. 177, MAYNE-00276588, at 591.
[146] Ex. 176, WC0164115, at 116.
[147] *Id.*
[148] Ex. 97, Kibbe Rpt. ¶ 31 n.19 (a desiccant is a packaging sachet that absorbs moisture).
[149] Ex. 178, WC00163441 (FDA letter approving the addition of the desiccant sachet).

[redacted][156]

c. Defendants' Dosing Flexibility Claims Are Baseless

Defendants may argue that introducing new dosage forms and strengths and adding scoring increased or improved dosing flexibility.[157] Throughout their anti-generic strategy, Defendants have actually reduced and eliminated dosing options available to consumers and doctors by removing prior versions from the market. For example, when the Defendants

[150] Ex. 179, WC0142211, at 214-16.
[151] *Id.* at 216.
[152] Ex. 43, MAYNE-000000287, at 289 (emphasis added).
[153] *Id.*
[154] *See* Ex. 52, MA-0261772, at 788; Ex. 180, MA-0000834, at 836.
[155] Ex. 75, Lukas Dep. 208:4-9; Ex. 181, Jasti Dep. 92:17-24; Ex. 182, Robbins Dep. 44:11-13.
[156] Ex. 171, MAYNE-00007380, at 381.
[157] *See, e.g.*, Ex. 156, Robbins Rpt. ¶¶ 27-30.

switched the market to dual-scored 150 mg tablets, [redacted][158]

By switching to the 75mg and 100mg unscored tablets and discontinuing the capsules, [redacted][159] Those patients that preferred capsules in general, or suffered health issues because of swallowing the tablets also lost the choice of capsules.[160] After the approval of the 150 mg tablet, [redacted][163] For most customers, this switch essentially eliminated several dosing options, including the most frequently prescribed 100 mg dose. Further, since the approval of the dual scored tablet and cessation of production of the single-scored 150 mg, the 75 mg dose has not been available.[164]

D. The Anti-Generic Strategy Prevented Entry by Mylan

Mylan had first considered the development of a generic Doryx capsule product in [redacted] and formally authorized development of the product in [redacted][165] [redacted][167]

[158] *See* Ex. 29, Webster Dep. at 436:7-437:24.
[159] [redacted]
[160] *See* Ex. 92, WC1649176; Ex. 93, MA-0063782, at 785-87; Ex. 94, WC0029977, at 977-78.
[161] *See* Ex. 128, WC3800932; Ex. 184, WC0745156, Slides 37-40; Ex. 185, WC1533024, at 024.
[162] Ex. 186, MA-0007545; Ex. 70, MA-0551635; Ex. 188, WC1869396.
[163] *See* Ex. 189, WC1089058; Ex. 129, WC1295637, at 637.
[164] Ex. 97, Kibbe Rpt. ¶ 77. *See also* Ex. 189, WC1089058; Ex. 190, http://www.wcrx.com/products/doryx/acne.jsp (Doryx website only advertising 200 mg and 100 mg Doryx doses).
[165] Ex. 191, MYLAN-00300145; Ex. 192, MYLAN-00100193; Ex. 193, MYLAN-01395471.
[166] Ex. 194, MYLAN-00100255, at 256.
[167] Ex. 195, MYLAN-00100709; Ex. 196, MYL-DX015608, at 613; Ex. 197, MYL-DX014232, at 238.

However, when Defendants made the switch from capsules to tablets, Mylan determined that a re-formulation to tablets would be required due to the elimination of the market for capsules.[168]

By [redacted], Mylan had prepared a tablet formulation; [redacted][169] But as a result of Defendants' delay in securing labeling for applesauce dosing of Doryx tablets, Mylan had to change the formulation [redacted][170] Mylan therefore developed a tablet form that could be labeled for applesauce dosing.[171] [redacted][172] Mylan submitted an ANDA on March 31, 2008, [redacted].[173] However, Defendants added score lines to their product and filed a Citizen Petition requesting that the FDA require any generic version also have scoring.[174] The FDA informed Mylan that it was required to add score lines to its product and conduct additional testing.[175] Mylan added the score lines and amended its ANDA on March 20, 2009, and April 23, 2009.[176] On December 28, 2010, the FDA approved Mylan's 75 mg and 100 mg doxycycline hyclate delayed-release tablets.[177] The FDA acknowledged that the approval of Mylan's product had been delayed by Defendants' conduct.[178]

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[168] Ex. 198, MYL-DX116338; Ex. 199, MYLAN-00101016, at 018; Ex. 200, Kirsch Dep. 149:7-10.
[169] Ex. 200, Kirsch Dep. 184:19-185:6; *see* Ex. 201, MYLAN-01225537, at 542.
[170] *See* Ex. 202, MYLAN-00400874, Slides 2, 9; Ex. 203, MYLAN-01868454, Slide 12; Ex. 200, Kirsch Dep. 205:22-208:9, 266:16-267:3.
[171] S*ee* Ex. 204, MYLAN-01617707, Slide 12; Ex. 203, MYLAN-01868454, Slide 12.
[172] *See* Ex. 205, MYLAN-00101744, at 744; Ex. 206, MYLAN-00101998, at 998.
[173] Ex. 207, MYLAN-00013059, at 059; Ex. 208, MYLAN-00815684, at 684.
[174] Ex. 209, WC1104469, at 469-75.
[175] Ex. 210, MYL-DX112655.
[176] Ex. 110, MYLAN-00011980; Ex. 211, MYLAN-00011976; Ex. 212, MYLAN-00011985.
[177] Ex. 213, MYLAN-00013318, at 318, 323.
[178] Ex. 214, WC3356994, at 994; Ex. 213, MYLAN-00013318, at 320 n.3 (noting that approval was delayed, in part, because "the requirements for approval were changed when [Doryx] was approved for a scored tablet configuration[.]").

By that time, Defendants had executed their switch to 150 mg tablets, meaning the market for 75 mg and 100 mg products was "shrinking" by the time Mylan entered.[179] Mylan had begun working on a 150 mg tablet in [redacted] submitted an ANDA on December 22, 2008, and received a tentative approval in June 2011.[180] In the meantime, Defendants sued Mylan for patent infringement and switched the market from a single-scored 150 mg tablet to a dual-scored 150 mg tablet.[181] Defendants filed another Citizen Petition with the FDA requesting that any ANDA applicant match the dual-scoring instead of the single-scoring, but the FDA rejected Defendants' request.[182] The FDA approved Mylan's 150 mg tablets on February 8, 2012, and Mylan launched shortly thereafter.[183]

It is undisputed that, if Defendants had not repeatedly switched the Doryx market, Mylan would have continued the development of a capsule product.[184] Mylan expected to submit an ANDA by [redacted] and would have been in a position to launch a generic Doryx capsule product during [redacted] absent Defendants' conduct.[185]

E. Prices in the Doryx Market Remained Artificially High as a Result of Defendants' Conduct

There can be no dispute that, absent Defendants' product hopping scheme, generic entry would have occurred more quickly and would have resulted in lower prices for health plans and

[179] Ex. 215, MYLAN-01935208; Ex. 216, MYLAN-00721630.
[180] Ex. 217, MYLAN-01869308; Ex. 218, MYLAN-00003251; Ex. 219, MYLAN-00017183, at 186.
[181] Ex. 220, MYLAN-00003230, at 230; Ex. 221, MYLAN-00000132, at 133.
[182] Ex. 222, WC1558119, at 119.
[183] Ex. 221, MYLAN-00000132, at 132, 135; Ex. 223, MYLAN-00614564.
[184] Ex. 200, Kirsch Dep. 148:18-153:14.
[185] *See* Ex. 224, MYLAN-00100973, at 975; Ex. 225, MYLAN-02190448, at 450; Ex. 226, Nelson Rebuttal Rpt. Ex. 61, Kirsch Decl. ¶ 7; *Id.* at Ex. 60, Talton Decl. ¶ 4.

patients.[186] Pharmaceutical economics literature shows that generic prices are well below the pre-entry price of the brand drug, and prices fall as additional generic producers enter.[187]

In this case, projections from Mylan [redacted] support the fact that prices would have fallen dramatically with the entry of multiple generic producers.[188] For example, [redacted][191] Indeed, the introduction of AB-rated generics in real life has led to decreased prices for delayed-release doxycycline hyclate. Since Mylan and Heritage's entry with AB-rated 150 mg tablets, price competition has continued to result in price reductions.[192]

Also, Defendants' conduct diverted resources that could have been used more productively.[193] [redacted]

[186] *See* Ex. 133, WC0567237, at 286 [redacted] *See also* Ex. 105, WC1810187, at 194; Ex. 102, MA-0693888, at 890.
[187] *See* Ex. 2, Rubinfeld Rpt. ¶ 82 & n.95 (citing literature); Ex. 19, Nelson Rpt. ¶ 203 & n.343.
[188] Ex. 227, MYLAN-02192580; Ex. 228, MYLAN-01540982, at Slides 21-22; [redacted]
[189] Ex. 227, MYLAN-02192580.
[190] *See* Ex. 229, MA-0156244, at Slides 8-9; Ex. 31, MA-0146074, at 074.
[191] Ex. 230, WC1727768; Ex. 231, WC2827412.
[192] Ex. 20, Rubinfeld Rebuttal Rpt. ¶ 20.
[193] Ex. 19, Nelson Rpt. ¶¶ 55, 209.
[194] Ex. 232, MAYNE-00001164, at 174.

[redacted][198]

Defendants' constant reformulations meant that millions of dollars were spent by Mylan and other generics to develop products that were rendered uneconomic.

III. STANDARD OF REVIEW

Summary judgment is proper if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[S]ummary judgment in favor of the party with the burden of persuasion is sometimes appropriate," for "[o]nce it appears that a reasonable jury must find each essential element of a violation and that there is no 'genuine issue' as to any legally material defense, there is no need for a trial." Ex. 235, 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 308f, at 12 (3d ed. 2013).

A violation of Section 1 of the Sherman Act consists of 1) a "contract, combination, . . . or conspiracy" that 2) "impose[s] an unreasonable restraint on trade." *Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc.*, 530 F.3d 204, 218 (3d Cir. 2008) (quoting 15 U.S.C. § 1). The elements of Section 2 monopolization are "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (internal marks and citation omitted). The elements of attempted monopolization are "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3)

[195] Ex. 233, WC0113591, at 596.
[196] Ex. 234, MA-0009532, at 538.
[197] Ex. 139, MA-0693206, at 210.
[198] *See* Ex. 68, WC1050706; *see also* Ex. 69, MA-0020886, at 892.

a dangerous probability of achieving monopoly power." *Id.* at 317 (internal marks and citation omitted).

IV. ARGUMENT

A. Defendants Possess Sufficient Market Power to Violate the Sherman Act

1. The Market Power Requirement

"Market power is 'the ability to raise prices above those that would prevail in a competitive market.'" *Toledo Mack*, 530 F.3d at 226 (citation omitted). For a Section 1 claim, a plaintiff may either show (1) direct evidence of anticompetitive effect from the conspiracy or (2) evidence that the conspirators possess market power sufficient to harm competition. *Id.* at 226. A Section 2 monopolization claim requires that the defendant possess monopoly power. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 186 (3d Cir. 2005). "[A] firm is a monopolist if it can profitably raise prices substantially above the competitive level." *Microsoft*, 253 F.3d at 51. Finally, attempted monopolization requires a "dangerous probability" that defendants will achieve monopoly power. *Broadcom*, 501 F.3d at 317. Control over prices and the ability to exclude competition can prove market power directly. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986); *Broadcom*, 501 F.3d at 317-18.[199] Alternatively, a high market share in a relevant market may provide indirect evidence of market power. *Id.*

2. Direct Evidence Establishes Defendants' Market Power

In *Broadcom*, the Third Circuit held that "[t]he existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output." 501 F.3d at 307. Moreover, the court recognized that, "[b]ecause market share and barriers to entry are merely surrogates for determining the existence of monopoly power, direct proof of monopoly power does not require a definition of the relevant market." 501 F.3d at 307 n.3 (citation omitted). This is in line with the approach of other circuits. *See Realcomp II*, 635 F.3d at 832.

[199] *See also Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 827-29 (6th Cir. 2011); *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 886-88 (N.D. Cal. 2011); *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000).

In this case, direct evidence reveals Defendants possess substantial market power. Dr. Rubinfeld's analysis shows that [redacted] and that generic entry has resulted in a substantial decline in prices for delayed-release doxycycline hyclate products. As Dr. Rubinfeld notes, "[t]he fact that average prices would have been lower in the but-for world is sufficient to demonstrate the competitive effects of Defendants' conduct[.]" Ex. 2, Rubinfeld Rpt. ¶ 66.

Dr. Rubinfeld examined a significant amount of direct evidence, including actual entry of generic Doryx, forecasts and analysts reports relating to generic Doryx entry, academic and government studies on the effect of generic entry into branded drug markets, as well as [redacted] *Id.* at ¶¶ 66-119. [redacted]

This evidence of actual supracompetitive pricing is bolstered by the additional evidence Dr. Rubinfeld examined. [redacted] at ¶¶ 71-81. Analyst reports, as well, have commented on Defendants' success in excluding competitors from the market. *Id.* at ¶¶ 93-95. [redacted] *Id.* at ¶¶ 83-92.

Dr. Addanki utterly fails to rebut any of this evidence, never contesting Dr. Rubinfeld's pricing analysis. Ex. 236, Addanki Dep. 104:11-105:6. Indeed, Dr. Addanki does not dispute that drastic pricing drops followed generic entry into the market. Rather, his analysis in this case

proffers a notion of monopoly power unheard of in antitrust law, asserting that the power to control prices is somehow not monopoly power if it is derived from branding efforts. Ex. 237, Addanki Rpt. ¶¶ 14-15; Ex. 20, Rubinfeld Rebuttal Rpt. ¶¶ 9-10; Ex. 226, Nelson Rebuttal Rpt. ¶¶ 17-20. This assertion is contrary to well-established law defining monopoly power and market power: courts have consistently held that the issue is power over pricing, regardless of the origins of this power. *See, e.g.*, *Toledo Mack*, 530 F.3d at 226; *Broadcom*, 501 F.3d at 307; *Microsoft Corp.*, 253 F.3d at 51. Dr. Addanki's argument conflates the question of whether a party *has* market power with the question of whether that power was illegally obtained or exploited.[200] His argument is, therefore, inapposite.

Moreover, Defendants' conduct in this case is inexplicable absent market power. [redacted][201] "A costly strategy designed to exclude a potential entrant would only be economically rational if the incumbent had substantial market power[.]" Ex. 2, Rubinfeld Rpt. ¶ 81 & n.94. If Doryx were competitively priced before generic entry, Defendants would not need to prevent generic entry, as it would have no effect on prices. The fact that Defendants had the ability and incentive to prevent generic entry through costly strategies in order to keep prices above the competitive level further demonstrates that Defendants possessed substantial market power over delayed-release doxycycline hyclate.

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[200] Even if Defendants' pricing power derived from branding efforts, this does not address Mylan's arguments that Defendants' subsequent efforts to preclude generic entry constituted illegal efforts to maintain monopoly power. As explained in Plaintiffs' *Daubert* motion, Dr. Addanki's approach to market power issues is so unreliable as to be inadmissible.

[201] [redacted]

3. Indirect Evidence Proves Defendants' Market Power

The evidence in this case also establishes that, at a minimum, Doryx and its AB-rated generics comprise a relevant antitrust submarket under *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962). *See In re Visa Check/MasterMoney Antitrust Litig.*, No. 96–CV–5238 (JG), 2003 WL 1712568, at *7 (E.D.N.Y. Apr. 1, 2003) (relying on *Brown Shoe* to hold "debit card services is a well-defined submarket[.]"). In *Brown Shoe*, the Supreme Court recognized that "well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes." 370 U.S. at 325. A submarket's boundaries are determined by "such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Id.*[202] Courts have frequently found that a specific pharmaceutical product can be a relevant antitrust market or sub-market. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (finding that relevant market limited to ciprofloxacin), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008).[203]

In this case, Dr. Nelson's economic reports and the medical testimony of Dr. James M. Jackson, demonstrate that Doryx is sufficiently differentiated in product characteristics, industry perception, and consumer preferences to constitute a distinct submarket for antitrust analysis. *See* Ex. 19, Nelson Rpt. ¶¶ 40-131; Ex. 226, Nelson Rebuttal Rpt. ¶¶ 21-41; Ex. 238, Jackson Rpt. ¶¶ 46-78; Ex. 239, Jackson Rebuttal Rpt. ¶¶ 6-26. In other words, the evidence shows "that the cross-elasticity of demand is low between Doryx and other acne drugs and, as a result, there is a well-defined antitrust market that only includes delayed-release doxycycline hyclate drugs."

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[202] The courts have continued to apply *Brown Shoe*'s analysis in antitrust cases. *See FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1039 (D.C. Cir. 2008) (submarket for premium natural and organic supermarkets); *United States v. H & R Block, Inc.*, 833 F. Supp. 2d 36, 53-54 (D.D.C. 2011); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1078-79 (D.D.C. 1997).

[203] *See also FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1238-41 (8th Cir. 2011); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000), *aff'd* 332 F.3d 896 (6th Cir. 2003).

Ex. 19, Nelson Rpt. ¶ 131. This also means that Doryx satisfies the Hypothetical Monopolist Test, meaning that a firm that controls all Doryx production could impose a small but significant nontransitory increase in price relative to the competitive level. *See* Ex. 240, U.S.D.O.J. & F.T.C., *Horizontal Merger Guidelines* § 4.1 (2010). For example, if Warner Chilcott was once again granted exclusive control over delayed-release doxycycline hyclate sales, it would have the ability and incentive to raise prices back to pre-generic levels.

Doctors rely upon numerous factors in prescribing oral antibiotics, including "the severity of the acne, the patient's skin type, age, and other conditions," and believe differences in the antibiotic's formulation significantly affect their patients' results. Ex. 19, Nelson Rpt. ¶ 46. Moreover, doctors tend to have preferences for particular treatments based upon their experience, and [redacted]Thus, for any given patient, doctors are unlikely to view the entire array of available antibiotics as equally interchangeable. *See id.* at ¶ 32.

Doryx offers unique benefits like reduced side effects due to its delayed-release properties, as discussed above. *See* Ex. 19, Nelson Rpt. ¶¶ 61-67. Accordingly, doctors and patients do not perceive other antibiotics as reasonably interchangeable with Doryx. *Id*. Moreover, even if a number of drugs are substitutable for certain patients, the existence of a substantial number of patients for which Doryx is the most appropriate product enables Defendants to maintain prices above the competitive levels. Ex. 226, Nelson Rebuttal Rpt. ¶ 22(b). Indeed, for patients suffering nausea and other gastrointestinal side effects from other tetracyclines, Doryx is the "only [product that] will do." *Whole Foods*, 548 F.3d at 351 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 574 (1996)). Such patients are, at a minimum, the type of "'distinct customers,' paying 'distinct prices,'" that antitrust courts have held supports a submarket finding. *Id.* at 352 (quoting *Brown Shoe*, 370 U.S. at 325).

Furthermore, the evidence indicating that Defendants perceived some competition from other products simply reflects the fact that purchasers will accept inferior substitutes at sufficiently high prices. *See Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451,

469-71 (1992) ("[T]he existence of significant substitution in the event of *further* price increases or even at the *current* price does not tell us whether the defendant *already* exercises significant market power[.]") (emphasis in original) (internal marks and citation omitted). Care must be taken in evaluating what are considered reasonably interchangeable substitutes, in order to avoid committing the "cellophane fallacy," that is, the error of construing substitution at prevailing prices as evidence of how competition would look at competitive prices. *See generally United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1121 (N.D. Cal. 2004) (describing cellophane fallacy). It is expected that more consumers would substitute away from Doryx in the face of supracompetitive prices than would substitute away had Doryx been competitively priced. *See* Ex. 19, Nelson Rpt. ¶¶ 129-130. Thus, the evidence in this case that Doryx and other products marketed against each other is more an effect of Doryx's monopolistic pricing than of reasonable interchangeablity.

Within this well-defined submarket of delayed-release doxycycline hyclate, Defendants held a 100% share prior to Mylan's entry, and continue to hold over [redacted] *Id.* at ¶ 181; Ex. 2, Rubinfeld Rpt. ¶ 115 & Ex. 11. These percentages are sufficient to demonstrate monopoly power. Indeed, courts have routinely held a market share of two-thirds or more to be dominant. *See, e.g.*, *Eastman Kodak*, 504 U.S. at 481 (80-95%); *Grinnell*, 384 U.S. at 571 (87%); *United States v. E.I. du Pont Nemours & Co.*, 351 U.S. 377, 379 (1956) (75%); *Am. Tobacco Co. v. United States*, 328 U.S. 781 (1946) (over 66%); *Microsoft Corp.*, 253 F.3d at 54 (80% or 95%); *Dentsply*, 399 F.3d at 188 (75-80%).

Moreover, the significant barriers to entry in this case demonstrate that Defendants' market power was durable. *See Microsoft*, 253 F.3d at 51 ("[M]onopoly power may be inferred from a firm's possession of a dominant share of a relevant market that is protected by entry barriers."). It is nearly universally recognized that pharmaceutical markets are characterized by high technical and regulatory barriers to entry. *See* Ex. 2, Rubinfeld Rpt. ¶¶ 14-20; Ex. 19, Nelson Rpt. ¶ 169. This case is no exception, especially in light of [redacted] and Defendants' ability to successfully game the

regulatory system. *See* Ex. 19, Nelson Rpt. ¶¶ 138-44; *id.* at ¶ 166 [redacted] *id.* ¶ 170 ("[T]he need to develop essential technical knowhow, the need for regulatory approvals, and the conduct of [Defendants] all are significant barriers to entry in the market for delayed-release doxycycline hyclate."). Defendant's substantial market power was thus protected by technical and regulatory barriers.

B. The Purpose and Effect of Defendants' Conduct was Exclusion of Competition and Maintenance of High Prices

1. The Rule of Reason Applies

The next requirement for Mylan's antitrust claims is proof of anticompetitive conduct. "Conduct that impairs the opportunities of rivals and either does not further competition on the merits or does so in an unnecessarily restrictive way may be deemed anticompetitive." *Broadcom*, 501 F.3d at 308. *See also Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768, 784 (6th Cir. 2002) (citing *Caribbean Broad. Sys. Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998)). Conduct analysis under both Section 1 and Section 2 proceeds according to a well-established rule of reason; the plaintiff must make an initial showing of anticompetitive harm, then the burden shifts to the defendant to establish pro-competitive justifications for the conduct, and then the plaintiff must show that the harm to competition outweighs the benefits of any justifications the defendant has successfully proven. *See Microsoft*, 253 F.3d at 58-59 (describing rule of reason and noting symmetry of Section 1 rule of reason and Section 2 inquiries); *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007).

There is no rule of *per se* lawfulness for product changes. *Microsoft*, 253 F.3d at 65. Indeed, such a rule of *per se* lawfulness would be wholly inconsistent with recent Supreme Court precedent, which has consistently eschewed *per se* rules and reaffirmed the rule of reason as the ordinary standard for evaluating business conduct under the antitrust laws. *See, e.g., FTC v.*

Actavis, Inc., 133 S. Ct. 2223, 2230-38 (2013) (adopting rule of reason approach for pharmaceutical patent settlements); *Leegin*, 551 U.S. at 885-907.[204]

Multiple courts have, in fact, applied the rule of reason to evaluate the lawfulness of product changes under the antitrust laws. In *Kodak*, the Supreme Court held modifications to Kodak's copiers that excluded other potential after-market services could comprise exclusionary conduct under Section 2. *Kodak*, 504 U.S. at 483-86. Similarly, the D.C. Circuit in *Microsoft* held that Microsoft violated the antitrust laws by modifying its operating system to integrate Microsoft's Internet browser. 253 F.3d at 65-67. In *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340 (Fed. Cir. 1998), the Federal Circuit actually rejected liability on two more typical theories of exclusionary conduct (fraud in obtaining a patent and sham litigation) but affirmed a finding of antitrust liability under the rule of reason for modifications to a patented needle gun in order to exclude competing needles. *Id*. at 1382. And the court in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (*TriCor*), found that pharmaceutical product hopping should be evaluated under the rule of reason. *Id*. at 422. In the face of such substantial authority, Defendants' proposed rule of *per se* lawfulness for product changes cannot stand.

2. Product Hopping Can Violate the Rule of Reason

"[T]he anticompetitive effects of [generic pharmaceutical] exclusion cannot be seriously debated." *Valley Drug*, 344 F.3d at 1311 n.27; *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, at 910 (6th Cir. 2003). This is because a lack of generic entry on branded products ensures prices will remain high to consumers, preventing them from realizing the substantial cost savings associated with AB-rated generic entry. *See* Ex. 2, Rubinfeld Rpt. ¶¶ 26-29; Ex. 19, Nelson Rpt. ¶¶ 190-208.

[204] As described in Mylan's *Daubert* motion, Defendants' testimony on competitive effects from Dr. Dennis Carlton is contrary to law, and thus inadmissible, as it hinges on his view that product changes can almost never be anticompetitive even if the sole effect of the changes is to exclude competitors and maintain supracompetitive prices. Ex. 242, Carlton Rpt. ¶¶ 24-27, 44-53; Ex. 243, Carlton Dep. 116:13-125:22, 277:4-15.

Delayed generic entry due to product hopping undermines the Hatch-Waxman Act's policy goals. "A central purpose of the Hatch-Waxman Act . . . is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'" *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)); *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

Product hopping also thwarts state substitution laws by preventing automatic substitution. All states allow substitution by pharmacists of AB-rated generics for branded prescriptions, and some states require it. For example, Pennsylvania enacted mandatory generic substitution "to permit consumers to secure necessary drugs at the most economical cost consistent with the professional discretion of the purchaser's physician and pharmacist." 35 P.S. § 960.1.

By design, substitution is the most efficient means for generic pharmaceuticals to compete in the market; eliminating substitution for all intents and purposes means eliminating lower-cost generic competition. *See TriCor*, 432 F. Supp. 2d at 423 ("To show that conduct has an anticompetitive effect, 'it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.' . . . Competitors need not be barred 'from all means of distribution,' if they are barred 'from the cost-efficient ones.'") (quoting *Dentsply*, 399 F.3d at 191, and *Microsoft*, 253 F.3d at 64). Conduct that inhibits generic substitution thus causes the exact type of harm to consumer welfare the antitrust laws were meant to prevent.

Accordingly, courts, regulators, and scholars have noted the significant anticompetitive effects that product hopping strategies can have. In *TriCor*, the Court observed "while [generic producers] may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. . . . Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case." 432 F. Supp. 2d at 423. Similarly, the FTC has advised this Court that product hopping could harm competition, noting "[t]he potential for anticompetitive product redesign is particularly acute in

the pharmaceutical industry." FTC Amicus, at 12. This is consistent with its enforcement history, which includes a consent decree prohibiting Warner Chilcott from engaging in product hopping on certain drugs. *See* Ex. 244, *FTC v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-cv-02179-CKK, Dkt. No. 90, at 8 (D.D.C. Oct. 23, 2006).

A substantial body of scholarship also supports the view that product hopping can harm competition. The leading treatise on the intersection of intellectual property and antitrust law notes "product hopping to ward off generic competition is precisely the sort of behavior the Sherman Act condemns." Ex. 245, HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY & CHRISTOPHER R. LESLIE, IP & ANTITRUST § 15.3c1 (2d ed. 2011). Other published scholarly work likewise supports the proposition that product hopping can harm competition. *See* Ex. 1, Dogan & Lemley, 87 TEX. L. REV. at 714-16 ("Pharmaceutical product hopping presents a paradigmatic case of a regulatory game. . . . It makes no sense to immunize patently anticompetitive behavior because of the risk that some cases might prove tough to decide.").

Thus, product hopping to thwart generic competition constitutes unreasonable conduct under the antitrust laws. The proper approach is to apply the traditional rule of reason burden shifting framework. *See Microsoft*, 253 F.3d at 58-59; *Dentsply*, 399 F.3d at 187.

3. The Evidence Shows the Anticompetitive Purpose and Effects of Defendants' Conduct Conclusively

[redacted] Warner Chilcott executed a market switch from the capsule product to the tablet product in 2005, [redacted] Ex. 68, WC1050706; Ex. 69, MA-0020886, at 892. Notably, [redacted]

[redacted] Ex. 246, MAYNE-00108437, at 441, 444. *See also* Ex. 42, WC0300035, at 035 [redacted]

Defendants executed multiple strategies to enhance and build upon the anti-generic strategy they began with the capsule to tablet switch. [redacted] Through all of this, they had no regard for the views of the FDA on what was best for patients, but instead chose to pursue their anti-generic strategy at all costs [redacted]

As the evidence summarized above demonstrates, the purpose of Defendants' product hopping activities was to prevent generic entry and maintain high prices for Doryx. Their strategy succeeded, delaying large-scale generic entry on Doryx until 2011, years after it would have happened in the absence of Defendants' conduct. The conduct at issue blocked the most efficient pathway for entry of generic competition and prevented multiple potential generic entrants from coming into the market and ensuring higher prices. *See* Ex. 19, Nelson Rpt. ¶¶ 201-08. [redacted] Ex. 100, MA-0027383, at 383; Ex. 102, MA-0693888, at 890; Ex. 103, WC3469690, at 690. [redacted]

[redacted] Ex. 19, Nelson Rpt. ¶¶ 201-08 & Ex. 9B; Ex. 2, Rubinfeld Rpt. ¶¶ 66-122. Indeed, the evidence shows that Mylan's entry substantially reduced market-wide prices and that the recent entry of another generic Doryx product has reduced prices further. Ex. 19, Nelson Rpt. Ex. 9A-B; Ex. 20, Rubinfeld Rebuttal Rpt. ¶ 20. Simply put, once a "cost-efficient" mode of distribution for competitors became available, competition in the market for delayed-release doxycycline hyclate drove lower prices and increased consumer welfare. *See Microsoft*, 253 F.3d at 64.

4. Mylan Has Established the Conduct Elements of Its Antitrust Claims as a Matter of Law

The foregoing evidence meets Mylan's initial burden of showing anticompetitive conduct as a matter of law. The "anti-generic strategy" that Defendants pursued constitutes a conspiracy in restraint of trade under Section 1, and is unreasonable based on its anticompetitive effects in excluding competitors and preserving high prices. *See, e.g.*, *United States v. Visa USA, Inc.*, 344 F.3d 229, 240-41 (2d Cir. 2003) (exclusion of rival payment cards anticompetitive); *Toys "R" Us*, 221 F.3d at 937 (prevention of "price collapse" anticompetitive). It also constitutes anticompetitive conduct under Section 2, because it prevented new entry into the market and ensured prices remained above the levels that would have prevailed absent Defendants' conduct. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 286 (3d Cir. 2012) (driving rival out of market anticompetitive), *cert. denied*, 133 S. Ct. 2025 (2013); *Dentsply*, 399 F.3d at 191-96 (blocking new entry and expansion anticompetitive); *Conwood*, 290 F.3d at 789 (liability where "there was evidence showing that USTC's actions caused higher prices and reduced consumer choice, both of which are harmful to competition."). And Defendants' intent to monopolize cannot be doubted given their explicit goal of excluding lower-cost generic competition to maintain high prices, thus satisfying the intent element of an attempt claim (as well as giving a strong indicator of the likely competitive effects). *See Broadcom*, 501 F.3d at 318; *Microsoft*, 253 F.3d at 77; *Brown Shoe*, 370 U.S. at 329 n.48. Mylan's evidence is thus more than sufficient to find as a

matter of law that Defendants' conduct harmed competition, justifying liability under all three of Mylan's antitrust theories.

C. Defendants' Business Justifications are Invalid as a Matter of Law

Mylan's proof suffices to establish as a matter of law that Defendants' conduct harmed competition, meaning Defendants bear the burden of establishing "a nonpretextual claim that [their] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal[.]" *Microsoft*, 253 F.3d at 59; *LePage's Inc. v. 3M*, 324 F.3d 141, 164 (3d Cir. 2003) (*en banc*). "In general, a business justification is valid if it relates directly or indirectly to the enhancement of consumer welfare. Thus, pursuit of efficiency and quality control might be legitimate competitive reasons . . . , while the desire to maintain a monopoly market share or thwart the entry of competitors would not." *LePage's*, 324 F.3d at 163 (internal marks and citation omitted). Defendants' purported business justifications for their various anti-generic product-switching strategies concerning Doryx are all pretexual, post-hoc rationalizations that are invalid as a matter of law. *See Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1219 (9th Cir. 1997) ("Neither the aims of intellectual property law, nor the antitrust laws justify allowing a monopolist to rely upon a pretextual business justification to mask anticompetitive conduct.").

1. The Anti-Generic Switch From Capsules to Uncoated Tablets Did Not Improve Doryx

a. The Capsule-to-Tablet Switch Was Not Designed to Improve Esophageal Safety

None of Defendants' justifications for Warner Chilcott's capsule-to-tablet switch in the U.S. market are supportable. [redacted] *See* Ex. 242, Carlton Rpt. ¶ 35. But the *uncoated* Doryx tablets that Warner Chilcott developed and launched offer no cognizable advantage over the capsule as it would not prevent contact between the esophagus and the doxycycline hyclate. [redacted]

[redacted] *See* Ex. 250, MA-0665810, at 815.

Lastly, with respect to dosing with applesauce, Doryx tablets are a more challenging product for patients to use than Doryx capsules. Dosing with applesauce is easier with capsules, which [redacted] In contrast, taking a Doryx tablet with applesauce requires the patient to crush the tablet with a spoon or a pill crusher, [redacted]

b. The Capsule-to-Tablet Switch Was Not Designed to Improve Stability

Defendants also claim that Doryx tablets had improved stability compared to Doryx capsules. However, stability improvement was *not* among the goals of Defendant's anti-generic, capsule-to-tablet reformulation. [redacted]

[redacted]

[redacted] Ex. 97, Kibbe Rpt. ¶¶ 35-36. The Doryx tablets were ultimately approved for the *same* 24-month shelf life as Doryx capsules. *See* Ex. 182, Robbins Dep. 87:14-88:8. Thus, they had the same shelf life [redacted] *See* Ex. 77, MA-0022039. Defendants therefore cannot argue that stability improvement leading to increased product shelf life was a goal for their anti-generic capsule-to-tablet reformulation effort.

c. Regulatory Risks in Non-U.S. Markets Did Not Motivate Defendants' Capsule-to-Tablet Switch in the U.S. Market

[redacted] This post-hoc, litigation-driven argument fails for several reasons.

[redacted][205]

[205] [redacted]

[redacted]

Third, Doryx tablets have never been sold outside of the United States. *See* Ex. 45, MA-0122173, at 176. Foreign markets have always been supplied with Doryx capsules instead. *See* Ex. 226, Nelson Rebuttal Rpt. ¶ 57(c). A global problem should have resulted in a global solution, but the tablets were only introduced in the U.S. where Defendants could game the regulatory system. Thus, Defendants cannot credibly argue that the introduction of Doryx tablets in non-U.S. markets was a significant motivator for Warner Chilcott's tablet development in the U.S.

d. The Capsule-to-Tablet Switch Did Not Improve the Product

Defendants' capsule-to-tablet switch did not improve the Doryx product and, if anything, introduced new challenges regarding ease of swallowing and [redacted] Doryx tablets are larger and thus not easier to swallow than Doryx capsules. Ex. 97, Kibbe Rpt. ¶¶ 10, 41-45, & Ex. C. Both intuition and simple math indicate that, if anything, Doryx tablets are probably more difficult to swallow than capsules of comparable dosage on account of the tablets' significantly larger volume.[207] [redacted] *ee* Ex. 256, WC0006174, at 176; Ex. 257, WC-0437290, at 291.

While some studies suggest *coated* tablets are easier to swallow than capsules, Doryx tablets are *not* coated. In fact, [redacted]

[206] [redacted]

[207] The 100 mg Doryx tablet, while slightly shorter than the 100 mg capsule, is *43% wider* than the 100 mg capsule and *10% thicker*, meaning the Doryx tablet is a much larger volume to swallow. Ex. 97, Kibbe Rpt. ¶ 42 & n. 34.

[redacted] *See* Ex. 161, MAYNE-00118510; Ex. 162, WC0175921.

[redacted]

e. Defendants' Continued Marketing of Capsules Outside the U.S. and [redacted] Confirm that Anti-Generic Strategy, Not Safety Concerns, Motivated Their Capsule-to-Tablet Switch

Defendants' own actions further confirm that their capsule-to-tablet switch did not improve the Doryx product. The continued use of capsules in Australia and Singapore is contrary to the claim that serious health issues motivated Defendants to switch from capsules to tablets. [redacted]

[redacted]

The only rational explanation for Defendants' inconsistent conduct is that safety concerns did *not* play a part in Defendants' removal of capsules from the U.S. market. Rather, their capsule-to-tablet switch was by Defendants' own admission [redacted] Ex. 260, McNamara Dep. at 99:5-13.

2. Other Anti-Generic Switches Did Not Improve the Product

Besides Defendants' removal of Doryx capsules from the market and strategic switch to tablets to protect Doryx sales, their other anti-generic switches—such as developing the 150 mg tablet, or scoring their 75 mg, 100 mg, and 150 mg tablets—did not improve the product. Moreover, any problems that such product switches may have solved were created by Defendants' own conduct in the first place. They cannot, therefore, rely on problems created by their own anticompetitive conduct to justify the further steps in their anti-generic strategy.

For example, Defendants claim that adding a score line to the 75 mg and 100 mg tablets allows for greater dosing flexibility, in the sense that patients could take a 37.5 mg and a 50 mg dosage, respectively, by breaking the tablets in half. As for the 37.5 mg dosage, or the originally available 75 mg dosage for that matter, these options were eliminated when Defendants discontinued the 75 mg Doryx tablet and the 150 mg single-scored Doryx tablet, and launched the double-scored 150 mg Doryx tablet. *See* Ex. 261, WC0262307, at 308. The elimination of the 37.5 mg dosing option invites doubt as to the justification for it in the first place, and the elimination of the 75 mg dosing option—which had been available since 2001—has never been

explained. Defendants' persistent dosage switching eliminated most of Defendants' claimed benefits of dosing flexibility and potentially caused confusion among physicians. [redacted]

Defendants' argument that adding a score line to Doryx tablets increases dosage flexibility is further undermined by the fact that a 50 mg capsule has been sold in Australia for decades, and Doryx had been available in the United States for more than 20 years without a 50 mg dose. If Defendants wanted to introduce the 50 mg dose into the United States, the most efficient way would have been to seek approval for the 50 mg capsule dose that was already approved and sold in Australia. [redacted] *See* Ex. 232, MAYNE-00001164, at 174; Ex. 233, WC0113591, at 596; Ex. 234, MA-0009532, at 538; Ex. 139, MA-0693206, at 210.

3. Avoidance of "Free-Riding" Is Not A Valid Defense

Defendants' experts characterize generic manufacturers' reliance on generic substitution as "passive," "misguided," and impermissible "free-riding." Ex. 262, Moe Rpt. ¶¶ 53-54, 70; Ex. 263, Gottlieb Rpt. ¶ 32. Because brand manufacturers' development and promotion of brand drugs are costly undertakings, so the argument goes, Defendants' anti-generic conduct is meant to deter generic manufacturers from "free-riding" on such undertakings and therefore justified.

The FTC, which has well-developed expertise in antitrust issues in pharmaceuticals, thoroughly discredited this argument in its amicus brief earlier in these proceedings. It noted that the Hatch-Waxman Act and state substitution laws "create a regulatory framework designed to reduce costs for consumers by lowering generic costs and increasing the role of price at the retail pharmacy counter." FTC Amicus, at 7. As Defendants' expert Dr. Kolassa admits (Ex. 87, Kolassa Dep. 297:14-298:24), the generics industry is structured so that products can be sold at a dramatically lower price, and state drug product selection ("DPS") laws work in concert to enable generic competition by providing the most cost-efficient system to distribute generics to

the marketplace and consumers. Ex. 5, Johnston Rpt. ¶ 46. In other words, and as the FTC succinctly states, "[w]hatever 'free-riding' occurs [] is the intended result of the legislative framework of the Hatch-Waxman Act and the state substitution laws." FTC Amicus, at 7. Defendants' free-riding argument hinges on "a misunderstanding of the role of free-riding analysis in antitrust law." *See Premier Elec. Const. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 368-69 (7th Cir. 1987). Free-riding analysis "is usually used in vertical chains of distribution," where "[t]o prevent [distributors] from abandoning the service that consumers value, the manufacturer may limit who can sell the goods and where." *Id.* at 369.

That is not the circumstance here, where Defendants merely seek to preserve their supra-competitive prices. "A group of firms trying to extract a supra-competitive price therefore hardly can turn around and try to squelch lower prices . . . by branding the lower prices 'free riding'!" *Id.* at 370. Moreover, generic substitution is a type of "free-riding" the law endorses and encourages. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1051-52 (N.D. Ill. 2003) (Posner, J.) ("[T]hat kind of free riding the law permits, and indeed the Hatch-Waxman Act encourages."), *overruled on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005). *See also Teva Pharms. USA, Inc. v. Abbott Labs.*, Civ. Nos. 02–1512–SLR, 03–120–SLR, 05–340–SLR, 2008 WL 4809116, at *2 (D. Del. Nov. 5, 2008) ("[T]he Hatch–Waxman Act establishes and condones . . . the 'piggybacking' of generics.").

This Court indicated in its order on Defendants' motion to dismiss that it was "skeptical that the 'product hopping' alleged here constitutes anticompetitive conduct under the Sherman Act" based on Defendants' claim that "[n]othing [they] have done precludes generic firms from making and advertising their own versions of doxycycline hyclate to compete with Doryx." Dkt. No. 280, at 3-4. The evidence developed through discovery proves conclusively that Defendants' assertions had no foundation, and that the Court was exactly right to await a full factual record before adjudicating them. As Dr. Nelson notes, "the fact that Mylan is not physically restrained from introducing generic Doryx capsules does not mean that Defendants'

conduct is not designed to 'prevent' or delay entry or did not have the effect of 'preventing' or delaying entry." Ex. 226, Nelson Rebuttal Rpt. ¶ 75. This is so because, in light of the regulatory framework in which pharmaceutical companies compete, "Defendants' anti-generic conduct made Mylan's introduction of a generic capsule uneconomic, which 'prevented' pro-competitive generic entry into delayed-release doxycycline hyclate capsules[.]" *Id*.

Moreover, marketing of generic pharmaceutical products is virtually non-existent as the cost associated with detailing physicians and other extraordinary marketing tactics would essentially eliminate the cost savings associated with generic entry and any marketing of a generic would likely redound to the benefit of other manufacturers. Ex. 2, Rubinfeld Rpt. ¶¶ 28-29. The handful of examples Defendants have pointed to are plainly exceptional cases, and their own industry expert agrees that promotional activities generally do not make sense for generic companies. *See* Ex. 226, Nelson Rebuttal Rpt. ¶ 78.

There is simply no reason to believe (and no evidence to suggest) that Mylan (or any other generic) could have economically marketed a non-AB-rated generic Doryx product to any stakeholder, whether payors or health-care providers, because such efforts would have benefitted other generic manufacturers just as much. *See id*. at ¶¶ 74-79, 95-98; Ex. 20, Rubinfeld Rebuttal Rpt. ¶¶ 12-19; Ex. 264, Cestra Dep. 102:4-25; Ex. 265, Harper Dep. 131:19-135:9. Specifically, had Mylan (or some other generic) embarked on a costly detailing or marketing campaign, the exercise would have been uneconomic. The attraction of generics is in their low cost and therefore low price appeal. Adding the extensive layer of costs, on which Defendants insist, would have increased the cost and therefore the price of any would-be generic entrant, rendering the product no longer attractive. And, a generic company that engaged in such marketing could not ensure that pharmacists dispensed its generic product as opposed to one made by another generic company. No rational company would have undertaken these expenses given the lack of any expectation of a return on the investment – and, in fact, generic suppliers do not do so.

Thus, any claim that Defendants' plainly anticompetitive conduct was justified by the implausible possibility that a generic could try to compete for Doryx sales other than through the

efficient pathway established by the Hatch-Waxman Act and state substitution laws must fail. *See Dentsply*, 399 F.3d at 191 ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."); *Microsoft*, 253 F.3d at 64 ("[A]lthough Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones.").

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Defendants' business justifications are entirely pretextual, and in any event the massive consumer harm caused by their "anti-generic strategy" far outweighs any possible benefits their strategic product changes may have conferred. *See TriCor*, 432 F. Supp. 2d at 422 ("Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants."). Mylan has thus satisfied the conduct elements of its Sherman Act claims as a matter of law.

D. Defendants' Single Entity Defense is Foreclosed by *American Needle*

1. *American Needle* Requires a Functional Analysis

The Supreme Court recently addressed the single entity defense in *American Needle, Inc. v. National Football League*, 560 U.S. 183 (2010), and rejected the notion that an entity could be immune from § 1 liability based solely upon its legal structure. *See id.* at 190-92; *see also Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 773 n.21 (1984) ("[S]ubstance, not form, should determine whether a[n] . . . entity is capable of conspiring under § 1."). The Court found that National Football League Properties (NFLP), which consisted of all the NFL teams and which developed, licensed, and marketed the teams' names, colors, trademarks, and related intellectual property, could violate Section 1.

Holding that "[t]he relevant inquiry . . . is whether there is a 'contract, combination . . . or conspiracy' amongst 'separate economic actors pursuing separate economic interests' such that

the agreement 'deprives the marketplace of independent centers of decisionmaking,'" the Court found the NFL teams acting through NFLP did "not possess either the unitary decisionmaking quality or the single aggregation of economic power characteristic of independent action." *Am. Needle*, 560 U.S. at 195-96 (citations omitted). The Court instead found that "[c]ommon interests in the NFL brand '*partially* unit[ed] the economic interests of the parent firms', but the teams still have distinct, potentially competing interests." *Id.* at 198 (emphasis in original) (citation omitted). And it recognized that "'[a]lthough the business interests of' the teams 'will *often* coincide with those of the' NFLP 'as an entity in itself, that commonality of interest exists in every cartel.'" *Id.* at 201 (emphasis in original) (quoting *Los Angeles Mem'l Coliseum Comm'n v. NFL*, 726 F.2d 1381, 1389 (9th Cir. 1984)).

Since *American Needle*, federal courts have consistently applied the functional analysis it espoused. The Third Circuit, for example, recently applied *American Needle* to find the Association of Tennis Professionals (ATP) was capable of violating § 1. *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820 (3d Cir. 2010). That court noted that "formalities should not detract from the necessity to examine the economic realities of the restraints imposed on competition[.]" *Id.* at 835. Similarly, the Fourth Circuit recently held that "concerted action is satisfied when an agreement exists between separate economic actors' such that any agreement 'deprives the marketplace of independent centers of decisionmaking.'" *North Carolina State Bd. of Dental Examiners v. FTC*, 717 F.3d 359, 371 (4th Cir. 2013) (quoting *Am. Needle*, 560 U.S. at 195), *cert. granted*, No. 13-534, 2014 WL 801099 (Mar. 3, 2014).

2. The Evidence is Conclusive That Defendants are Independent Centers of Decisionmaking

Here, as in *American Needle*, there is no evidence that Defendants "possess either the unitary decisionmaking quality or the single aggregation of economic power characteristic of independent action." 560 U.S. at 195-96. Defendants rely solely upon their exclusive licensing agreement to contend that they are a single entity incapable of conspiracy. But as the Supreme

Court has repeatedly held, a mere agreement is insufficient to preclude § 1 liability. *Id.* at 190-92; *Copperweld*, 467 U.S. at 752.

A functional analysis of the Defendants' relationship clearly shows they are separate centers of economic decisionmaking with a diversity of entrepreneurial interests. [redacted]

Defendants, moreover, cannot demonstrate the complete unity of interests needed for a viable single entity defense. *See Am. Needle*, 560 U.S. at 195-97. [redacted]

Moreover, as in *American Needle*, it is undisputed here that Mayne and Warner Chilcott are "still separate, profit-maximizing entities," despite their occasionally common interests. 560 U.S. at 198. The Defendants each continue to independently operate their own companies and to seek to maximize their individual profits, [redacted] *See, e.g.*, Ex. 268, MA-0693585; Ex. 269, WC3156774; Ex. 270, MA-0023876; Ex. 271, MA-00009884. [redacted]

[redacted] Accordingly, the evidence in the record clearly establishes Defendants are independent decisionmakers capable of conspiring.

E. Mylan Suffered Antitrust Injury From Defendants' Conduct

"In addition to establishing a statutory violation, a plaintiff must demonstrate that it suffered antitrust injury." *ZF Meritor*, 696 F.3d at 281. This requires proof of "(1) harm of the type the antitrust laws were intended to prevent; and (2) an injury to the plaintiff which flows from that which makes defendant's acts unlawful." *Id.* (internal marks and citation omitted). Competitors who are excluded from the market by an antitrust violation suffer antitrust injury. *See id.* at 289; *Hammes v. AAMCO Transmissions, Inc.*, 33 F.3d 774, 782-83 (7th Cir. 1994) (Posner, J.) (plaintiff that "wanted to compete by underselling" defendants incurs antitrust injury).

Mylan indisputably suffered antitrust injury. Mylan repeatedly had to alter its product development efforts in response to Defendants' product hopping, incurring additional expenses and delaying its development timeline. *See* Part II.D, *supra*, and exhibits cited therein. Supported by the testimony of Mylan employees, data on Mylan's previous product launches, and other evidence, Dr. Nelson estimates that Mylan would have entered in [redacted] years earlier than it actually entered. *See* Ex. 19, Nelson Rpt. ¶¶ 210-14; Ex. 226, Nelson Rebuttal Rpt. ¶¶ 90-137. As the first generic manufacturer to actually enter on a large scale, Mylan's exclusion from the market was one of the main anticompetitive effects of Defendants' conduct. *See TriCor*, 432 F. Supp. 2d at 431 ("Such exclusion from the market is 'precisely the type of injury that the antitrust laws were intended to prevent,' because it reflects an injury to competition.") (quoting *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 772 (D.N.J. 1999)).

Defendants may argue against the details of Mylan's but-for world, but they ultimately cannot contest that Mylan would have brought a generic version of Doryx to market earlier

absent Defendants' anticompetitive conduct. Defendants' arguments thus go solely to the degree of impact, i.e., damages, not to the fact that Mylan suffered antitrust injury from Defendants' anticompetitive conduct. *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 356 (D.N.J. 2009) ("'It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury.' . . . [R]equiring otherwise 'would effectively deny private remedies, because multiple causes always affect everyone.'") (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969) and 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 338a at 317 (2d ed. 2000)).

V. CONCLUSION

Defendants purposefully undertook a course of conduct directed at excluding competitors and ensuring ongoing supracompetitive profits at the expense of consumers. Their conduct did exactly that, and harmed Mylan in the process due to its exclusion from the market for delayed-release doxycycline hyclate products. None of their legally relevant defenses has sufficient factual support to justify a trial, so Mylan's Motion for Summary Judgment should be granted.

Dated: March 10, 2014

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., et al.,	:	
	:	
Plaintiffs,	:	
	:	**Civ. No. 12-3824**
v.	:	**CONSOLIDATED**
	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
	:	
	:	
Defendants.	:	
	:	
	:	

[PROPOSED] ORDER

AND NOW, this ____ day of _____, 2014, upon consideration of Plaintiff Mylan Pharmaceuticals, Inc.'s Motion for Summary Judgment as to Defendants' Antitrust Liability, it is hereby ORDERED that said Motion is GRANTED. Defendants are liable to Plaintiff as a matter of law, and the trial of Plaintiff's claims will be limited to determining the amount of damages owed and resolving Plaintiff's state law claim.

BY THE COURT,

_____

Hon. Paul S. Diamond